K062673

510(k)

SEP 22 2006

SECTION 9 **510(k) SUMMARY**

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

I. GENERAL INFORMATION

1. Device Name and Classification

Product Name:	***syngo® InSpace 4D***
Classification Name:	Computed tomography x-ray system
Classification Panel:	Radiology
CFR Section:	21 CFR §892.1750
Device Class:	Class II
Product Code:	JAK

2. Importer/Distributor Establishment:

Registration Number: 2240869

Siemens Medical Solutions, Inc.
51 Valley Stream Pkwy
Malvern, PA 19355

3. Manufacturing Facility:

Siemens AG
Wittelsbacherplatz 2
D-80333 Muenchen, Germany

4. Contact Person:

Mr. Rüdiger Körner
Manager Regulatory Submissions
Siemensstr.1; D-91301 Forchheim
Phone: +49 9191 18-9355
Fax: +49 9191 18-9782

5. Date of Preparation of Summary: May 18th, 2006

II. SAFETY AND EFFECTIVENESS INFORMATION SUPPORTING THE SUBSTANTIAL EQUIVALENCE DETERMINATION

1. General Safety and Effectiveness Concerns

The device labeling contains instructions for use and any necessary cautions and warnings, to provide for safe and effective use of the device.

Risk management is ensured via a hazard analysis, which is used to identify potential hazards. These potential hazards are controlled via software development, verification and validation testing. To minimize electrical, mechanical, and radiation hazards, Siemens adheres to recognized and established industry practice and standards.

2. Substantial Equivalence

The ***syngo® InSpace 4D*** Software Package, addressed in this pre-market notification, is substantially equivalent to the following commercially available software package:

Manufacturer	Product	510(k)	Clearance date
Siemens	InSpace 4D	K043469	02/03/2005

In summary, Siemens is of the opinion that *syngo® InSpace 4D* Software Package does not introduce any new potential safety risks and is substantially equivalent to and performs as well as the predicate software components and the predicate device.

3. Intended Use

The *syngo®* InSpace 4D software package is intended to assist the physician in skeletal and soft tissue imaging in addition to the originally approved indications.

4. Device Description

syngo® InSpace 4D - Software Package is a self-contained image analysis software package. This real-time interactive evaluation in space and time for CT volume data sets provides the reconstruction of two-dimensional images into a three-dimensional image format.

Syngo® InSpace can be used to assist the physician in the diagnosis of blood vessels on the basis of a CT Angiography dataset (CTA). For a CTA examination a contrast media (CM) is administered into the patient's blood vessels to enhance the contrast of the vessels in the CTA dataset, i.e. high values for the Hounsfield Unit (HU).

The goal is to visualize the blood vessels without other interfering anatomical structures.

The *syngo*® InSpace 4D is developed to facilitate a precise diagnosis by removing bone structures from a CTA data set. It can be used in the same way for Non CTA datasets to remove bones or extract and display selected bones, e.g. for the analysis of a fracture.

For a vascular evaluation the option Advanced Vessel Analysis (AVA) is designed to create an edited version of a volume to highlight and measure the vessels.

Additionally *syngo*® InSpace 4D is developed to facilitate fast and precise diagnosis by removing the CT table from a CT data set.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 19 2006

Siemens Medical Solutions, Inc.
% Mr. Olaf Teichert
Third Party Reviewer
TUV Product Service
1775 Old Highway 8 NW, Ste 104
NEW BRIGHTON MN 55112-1891

Re: K062673
Trade/Device Name: syngo® InSpace 4D
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: JAK
Dated: September 6, 2006
Received: September 8, 2006

Dear Mr. Teichert:

This letter corrects our substantially equivalent letter of September 22, 2006.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to continue marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

SECTION 3 INDICATION FOR USE

510(k) Number (if known): K062673

Device Name: ***syngo*® InSpace 4D**

Indications for Use:

***syngo*® InSpace 4D** - Software Package is a self-contained image analysis software package. This real-time interactive evaluation in space and time for CT volume data sets provides the reconstruction of two-dimensional images into a three-dimensional image format.

InSpace can be used to assist the physician in the diagnosis of blood vessels on the basis of a CT Angiography dataset (CTA). For a CTA examination a contrast media (CM) is administered into the patient's blood vessels to enhance the contrast of the vessels in the CTA dataset, i.e. high values for the Hounsfield Unit (HU).

The goal is to visualize the blood vessels without other interfering anatomical structures.

The ***syngo*® InSpace 4D** is developed to facilitate a precise diagnosis by removing bone structures from a CTA data set. It can be used in the same way for Non CTA datasets to remove bones or extract and display selected bones, e.g. for the analysis of a fracture.

Additionally ***syngo*® InSpace 4D** is developed to facilitate fast and precise diagnosis by removing the CT table from a CT data set.

Furthermore the ***syngo*® InSpace 4D** is embedded in the framework of a new server/client architecture also referred to as *syngo*® WebSpace. The server supports multiple sessions from remote "thin client" terminals at the same time. The thin client application is also a part of the *syngo*® WebSpace software suite, installed on a different computer, connected to the server by a network.

Prescription Use ____X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Marvin C Brogdon

Sign-Off)

of Reproductive, Abdominal, and

adiological Devices

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